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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,547	11/30/2000	Harri Jukarainen	TUR-101	5767

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EXAMINER

PENG, KUO LIANG

ART UNIT

PAPER NUMBER

1712

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,547	Applicant(s) JUKARAINEN ET AL.	
	Examiner Kuo-Liang Peng	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/01 IDS.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 1-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Applicants' preliminary amendment filed on November 30, 2000 was received.

Claims 3, 4, 6, 12, 14, 16-17, 20 and 22 are amended.

Specification

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

- (a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.
- (b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.
- (c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because of the following reason(s):

In lines 7-17 of page 2, it is not clear as to what "polysiloxane units" means because polysiloxane is a polymer which comprises siloxane units; as to what the relationship between "polysiloxane units" and "blocks" and as to what "these forms" means.

In line 15 of page 4, it is not clear as to what "partly free groups" refers to.

In line 25 of page 4, it is not clear as to what "partly bonds" refers to.

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In line 27 of page 4, it is not clear as to what "possibly partly unreacted groups" refers to.

In line 1 of page 5, it is not clear as to what "free" refers to.

3. The disclosure is objected to because of the following informalities:

In line 23 of page 4 and line 15 of page 5, should "1...30" be -- 1 to 30 --?

In line 23 of page 4, should "alkyl" be -- alkylene --?

In line 29 of page 4, should "1...3000" be -- 1 to 3000 --?

In line 14 of page 14, should "2...6" be -- 2 to 6 --?

In line 13 of page 4, should $-(\text{SiR}'\text{R}''\text{O})_q\text{SiR}'\text{R}''-$ be $-(\text{SiR}'\text{R}''\text{O})_q--$? Otherwise, the polymer will contain a Si-Si bond that is a silane linkage rather than a siloxane linkage.

Appropriate correction is required.

Claim Objections

4. Claims 1-22 are objected to because of the following informalities:

In Claims 4, 7, 10 and 20, Applicants are advised to remove the unnecessary symbol (i.e., "--").

In lines 4-5 of Claim 1, lines 1-2 of Claim 2, lines 2-3 of Claim 3, lines 2-3 of Claim 4, lines 1-2 of Claim 5, lines 1-2 of Claim 6, lines 1-2 of Claim 7, lines 1-2 of Claim 8, lines 1-2 of Claim 9, lines 1-2 of Claim 10, lines 1-2 of Claim 11, lines 1-2 of Claim 12, lines 1-2 of Claim 13, line 2 of Claim 14, line 1-2 of Claim 15, line 2 of Claim 16, line 2 of Claim 17, line 4 of

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Claim 18, line 1 of Claim 19, line 1-2 of Claim 20, line 1 of Claim 21 and lines 1-2 of Claim 22,

Applicants are advised to replace "characterized in that" with -- wherein --.

In line 6 of Claim 1, Applicants are advised to replace "that the" with -- said --.

In line 3 of Claim 4 and line 4 of Claim 12, should $-(\text{SiR}'\text{R}''\text{O})_q\text{SiR}'\text{R}''$ be -- $(\text{SiR}'\text{R}''\text{O})_q$ --? Otherwise, the polymer will contain Si-Si bonds that are silane linkages rather than siloxane linkages.

In line 4 of Claim 1 and line 3 of Claim 8, Applicants are advised to replace "possibly" with -- optionally --.

In line 2 of Claim 9, Applicants are advised to replace "possible" with -- optional --.

In line 7 of Claim 1, Applicants are advised to replace "the elastomer or polymer" with -- said elastomer or said non-crosslinked polymer --.

In line 7 of Claim 4, Applicants are advised to delete "the" between "case" and "said".

In line 13 of Claim 4, line 13 of Claim 12 and Claim 20 (page 37, line 20), should "1...30" be -- 1 to 30 --?

In line 13 of Claim 4, line 13 of Claim 12, line 11 of Claim 14 and Claim 20 (page 36, line 15 and page 37, line 19), should "alkyl" be -- alkylene --?

In line 18 of Claim 4, line 14 of Claim 12 and Claim 20 (page 35, line 25 and page 37, line 20), should "1...3000" be -- 1 to 3000 --?

In line 12 of Claims 6 and 14 and Claim 20 (page 35, line 25 and page 36, lines 16 and 26), should "1...30" be -- 1 to 30 --?

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In line 5 of Claim 9, line 7 of Claim 10, line 6 of Claim 12, line 6 of Claim 16, Claim 20 (page 34, line 30, page 35, line 10, page 36, lines 16 and 19 and page 37, line 10) and line 6 of Claim 21, Applicants are advised to delete "the" before "said".

In line 3 of Claim 16, Applicants are advised to replace ", and that" with -- wherein --.

In line 5 of Claim 19, Applicants are advised to replace "minimum" with -- least --.

In line 5 of Claim 20, should "R'-SiR'R'O(SiR'R'O)_rSiR'R'R'" be -- R'-SiR'R'O(SiR'R'O)_rSiR'R'R' --, as indicated in the specification (page 6, line 13).

In line 11 of Claim 20 and line 10 of Claim 21, Applicants are advised to replace "1...27000" with -- 1 to 27000 --.

In line 14 of Claim 20, Applicants are advised to remove "(I)".

In Claim 20, the definitions of "T", "A" and "B" in line 7 of page 35 are different from those in line 6 of page 37.

In Claim 20 (page 35, line 26 and page 37, line 20), Applicants are advised to replace "0...100" with -- 0 to 100 --.

In Claim 20, there are two definitions for R', i.e., one in page 36, lines 3-8 and the other in page 36, lines 9-11.

In Claim 20 (page 36, line 20), Applicants are advised to replace "1...5000" with -- 1 to 5000 --.

In Claim 20, Applicants are advised to remove "(II)" in page 37, line 6.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-5 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, lines 11-12 of claim 4, line 12 of Claim 12 and Claim 20 (page 36, line 14) recite the broad recitation "alk is a lower alkyl group", and the claim also recites "suitably methyl" which is the narrower statement of the range/limitation; claim 5 (lines 2-3) recites the broad recitation "a lower alkyl group", and the claim also recites "preferably methyl" which is the narrower statement of the range/limitation; and claim 13 (lines 2-3) recites the broad recitation "lower alkyl groups", and the claim also recites "preferably methyl" which is

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the narrower statement of the range/limitation; and lines 2-3 of Claim 17 and line 3 of Claim 22 recite the broad recitation "a filler", and the claim also recites "suitably silica" which is the narrower statement of the range/limitation

Claims 4 and 12 recite the limitation "the polysiloxane groups" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 5 and 13 recite the limitation "free R' and R'" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 4 (line 16), the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In lines 2-3 of Claim 1, line 11 of Claim 7, line 4 of Claim 10, line 2 of Claim 15, line 2 of Claim 16, line 1 of Claim 18 and line 12 of Claim 20, it is not clear as to what "siloxane-based elastomer" refers to. Applicants are advised to replace it with -- siloxane elastomer --.

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In lines 8 and 10 of Claim 1, line 3 of Claim 2, line 7 of Claim 7, lines 8 and 10 of Claim 10 and line 5 of Claim 16, it is not clear as to what “polysiloxane units” means because polysiloxane is a polymer, per se, which comprises siloxane units.

In lines 5-7 of Claim 9, it is not clear as to what “poly(dimethyl siloxane) units” means because poly(dimethyl siloxane) is a polymer, per se, which comprises dimethylsiloxane units.

In lines 8-9 of Claim 1, line 7 of Claim 7, line 5 of Claim 9, line 8-9 of Claim 10 and lines 5-6 of Claim 16, it is not clear as to what the relationship between “polysiloxane units” and “blocks”.

In lines 10-11 of Claim 1, line 9 of Claim 7, lines 7-8 of Claim 9, lines 10-11 of Claim 10 and lines 7-8 of Claim 16, it is not clear as to what “or as a mixture of these forms” means.

In line 5 of Claim 4, it is not clear as to what “partly free groups” refers to.

In line 14 of Claim 4, it is not clear as to what “partly bonds” refers to.

In line 16 of Claim 4, it is not clear as to what “possibly partly unreacted groups” means.

In line 2 of Claim 5 and line 2 of Claim 13, it is not clear as to what “free” refers to.

In line 2-3 of Claim 8 and line 3 of Claim 9, it is not clear as to what “a poly(dimethylsiloxane)-based elastomer” refers to. Applicants are advised to replace it with -- a poly(dimethylsiloxane) elastomer --.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-9 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 4,600,751).

With respect to Claims 1-2, Lee discloses a controlled-release membrane (col. 3, lines 3-12) potentially used for used in contact with humans (col. 7, lines 60-68) comprising A) a polysiloxane blocked and optionally grafted with poly(alkylene oxide) wherein the poly(alkylene oxide) blocks and grafts (if any) are one-end-capped with acryloxy groups and B) at least one substantially water insoluble aliphatically unsaturated organomonomer (col. 3, lines 15-63). In another embodiment, Lee further discloses a membrane containing only Component A) and containing no Component B) (Table I, Examples 1, 2 and 10). It is noted that the poly(alkylene oxide) blocks and poly(alkylene oxide) grafts are linked to the polysiloxanes via Si-C linkages (col. 3, lines 23-34 and col. 4, lines 65-68). It is further noted that Applicants' membrane or matrix is intended for use in controlled-release drugs. Therefore, to controlled-release drugs is an intention to use, which does not carry any patentability weight.

With respect to Claim 3, Lee further teaches that "d" can be 0 in the formula recited in col. 3, lines 23-34.

With respect to Claims 4-5, Lee further teaches that in the poly(alkylene oxide) grafts, "d" + "e" can be up to 30 (col. 3, lines 39-41 and col. 4, lines 65-68) and the number of siloxane repeating units in the polysiloxane can be up to 64 (i.e., "a" + "b") (col. 3, lines 36-37). R on the

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siloxane units can be a monovalent hydrocarbon of from 1 to 6 carbon atoms, which is free of aliphatic unsaturation. R' on the siloxane units can be methyl or phenyl (col. 3, lines 46-49).

With respect to Claim 6, Lee further teaches poly(alkylene oxide) blocks having the formula described in col. 3, lines 23-34, wherein "b" is 0; and "d" + "e" can be up to 30 (col. 3, lines 35-42).

With respect to Claims 7-9, Lee further teaches the use of a crosslinker (BCP-7) having the formula described in col. 17, lines 33-39 to crosslinked with BCP-1 (col. 9, lines 5-14). It is noted that the hydroxy groups in BCP-1 and BCP-7 are converted into acryloxy groups by IEM (col. 17, lines 49-51). It is noted that BCP-1 corresponds to "the first elastomer" in the instant claims and BCP-7 corresponds to "the second elastomer" in the instant claims, wherein BCP-1 and BCP-7 are crosslinked (i.e., "interlaced one inside the other").

With respect to Claim 17, Lee further teaches the use of a filler such as silica (col. 7, line 47).

With respect to Claim 18, Lee further teaches a method for the preparation of a siloxane elastomer which comprises poly(alkylene oxide) groups by crosslinked the siloxane elastomer with a peroxide (Examples 1-10 and col. 9, lines 27-33).

11. Claims 1-8, 10-18 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis (US 6,013,711).

With respect to Claims 1-2, Lewis discloses a matrix for medical use (col. 3, line 10) comprising a siloxane elastomer obtained by reacting a mixture comprising A1) a polyorganohydridosiloxane crosslinker that contains at least three SiH bonds per molecule (col.

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3, lines 33-34) and B3) a hydrophilic unsaturated siloxane-polyether copolymer (col. 3, line 49). Component B3) can be those described in col. 8, lines 19-36, wherein Z is a polyether containing group that is linked to the polysiloxane by a Si-C bond (col. 8, lines 65-67). It is noted that the formulae (F) and (G) (col. 8, lines 27-28) represent polysiloxane-polyether block copolymers; while the rest of the formulae represent polysiloxane-polyether graft copolymers. The polyether can be end-capped with a methyl group (col. 9, line 51-52). It is noted that Applicants' membrane or matrix is intended for use in controlled-release drugs. Therefore, to controlled-release drugs is an intention to use, which does not carry any patentability weight.

With respect to Claim 3, the polyether group can have the formula as described in col. 9, line 1, wherein a can be 2 (col. 9, line 4).

With respect to Claims 4 and 6, Lewis further teaches that Component B3) described in col. 8, lines 19-36 can have totally up to five silicone atoms (col. 8, lines 59-62) and the polyether groups in Component B3) can have 3 to 12 repeating oxyalkylene units (col. 9, line 13-14).

With respect to Claim 5, Lewis further teaches that Component B3) described in col. 8, lines 19-36 can have siloxane units having substituent (R) as C₁-C₁₂, saturated, monovalent organic group such as methyl group, phenyl group, etc. (col. 8, lines 38-48).

With respect to Claim 7, it is noted that the aforementioned Component B3) is crosslinked by Component A1), i.e., Component B3) and Component A1) are "interlaced one inside the other".

With respect to Claim 8, Component A1) can be represented by the formulae described in col. 4, line 64-66 to col. 5, line 1-5, wherein R can be a methyl group (col. 5, lines 10-11).

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With respect to Claims 10-16, Lewis further teaches the use of A4) a polydiorganosiloxane free of silanol or unsaturated groups (col. 3, lines 39-42), which does not react with other ingredients, i.e., it can only physically blended with B3) as rheology modifier (col. 7, lines 23-37).

With respect to Claim 17, Lewis further teaches the use of a filler (col. 3, line 43) such as silicas (col. 2, line 48).

With respect to Claim 18, Lewis further discloses a method for preparation of a siloxane elastomer by mixing a mixture comprising Component A1) and Component B3) and carrying out hydrosilylation reaction (Examples 40-44).

With respect to Claim 20, Lewis' Component B3) described in col. 8, lines 19-36 (i.e., (A) to (E)) reads on Applicants' I-c) set forth in the instant claim, and Lewis's Component A1) reads on Applicants' II-a) set forth in the instant claim.

With respect to Claim 21, Lewis' Component A1) having the formula described in col. 4, line 64 reads on Applicants' straight-chain hydride-functional siloxane copolymer.

With respect to Claim 22, Lewis further teaches the use of a filler (col. 3, line 43) such as silicas (col. 2, line 48).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis.

Lewis discloses a matrix for medical use as described in paragraph 11, which is incorporated herein by reference.

Applicants do not show the criticality of the ratio of the molar amount of hydrides to the molar amount of double bonds. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize whatever relative molar amount of hydrides and double bonds through routine experimentation in order to obtain whatever properties of the final product.

14. The “X” references cited in the international search report are not relied upon because of the following reasons:

Chemical Abstracts 126: 200000090, “Synthesis and Drug Release Property of Polysiloxane Containing Pendant Long Alkyl Ether Group” (1997) – does not teach a polysiloxane containing poly(oxyalkylene) grafts or blocks.

Katherine L. Ullman et al., “Drug Permeability of Modified Silicone Polymers I. Silicone-Organic Block Copolymers”, 10 J. Controlled Release 251-260 (1989) – does not teach a polysiloxane containing poly(oxyalkylene) grafts or blocks wherein the poly(oxyalkylene) linked to the polysiloxane with a Si-C linkage.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Kuo-Liang Peng

November 28, 2001


MARGARET G. MOORE
PRIMARY PATENT EXAMINE
ART UNIT 1712